

PSJ10 Exh 40

From: Jeff J Collins <jeffrey.collins@watson.com>
Sent: Wednesday, June 26, 2013 12:05 PM
To: Tom P Napoli
Cc: William Simmons
Subject: FW: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885
Attachments: Oxycodone sales may-june '13.txt; MIAMI-LUKEN INC SD# 636885 - CONTROLLED SUBSTANCE SALES HISTORY REPORT - 06 26 2013.xls; RE: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885; MIAMI-LUKEN INC SD# 636885 SOMS FORM.pdf

Tom,

I believe you are out of the office today, however I was hoping you would be able to take a look at this one and give some feedback. Miami-Luken has placed an order for 72 units of Oxy/APAP 10/650mg 100ct, this is on top of the 84 they have already received this month. Their allowable is 53 which would put them 103 over for the month. They sent along their sales for May 1-June 25 which was helpful and produced nothing extraordinary other than one customer.

McMeans #1 Ashland appears to be a local pharmacy in Ashland, Kentucky. They have ordered 42 units of this product during this time frame which accounts for 4,200 pills. This account jumps out as having purchased significantly more than the other which is why I'm asking. This is a small rural town of 21,000 people in the mountains of Kentucky. Do you have much knowledge of Miami-Luken's SOMS program and are you comfortable with this order?

Jeff

Jeffrey Collins
Investigator, Global Product Protection
Global Security & DEA Affairs, Actavis Inc (formerly Watson Pharmaceuticals)
605 Tri State Parkway, Gurnee, IL 60031
Office 847.377.5677 | Mobile 224.419.8504



From: Bettina C Dwor
Sent: Wednesday, June 26, 2013 1:28 PM
To: Jeff J Collins; Lynn DaCunha; Tom P Napoli
Cc: #Master Data Group; Vicky C Goldy; Maria Lesny; Bea Padilla; Judy L Callahan
Subject: FW: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885

For your review & approval, see attached SOMS form, Controlled Substance Sales History Report, & customer justification (see attached) for **00591082501 OXYCODONE/APAP 10/650MG TAB 100**. Please advise. Thanks!





Bettina C. Dwor
Master Data Administrator
Actavis
Morris Corporate Center III
400 Interpace Parkway, Bldg A
Parsippany, NJ 07054
P. 862.261.7071
F. 862.261.7808

From: Cindy Willet [<mailto:cwillet@miamiluken.com>]
Sent: Wednesday, June 26, 2013 2:21 PM
To: Bettina C Dwor
Subject: RE: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885

Please find attached our sales for the month of May-present day June. We have 12 bottles in stock.

Let me know if you need anything further.

Cindy

Cindy A. Willet
Sr. Buyer Generic & Branded Pharmaceuticals
Miami-Luken Inc.
265 S. Pioneer Blvd.
Springboro, OH 45066
Phone: 937-743-7775 x111
Fax: 888-884-4793
cwillet@miamiluken.com

From: Bettina C Dwor [<mailto:bettina.dwor@actavis.com>]
Sent: Wednesday, June 26, 2013 2:12 PM
To: cwillet
Subject: RE: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885

Hi, Cindy. This is a requirement of our DEA Affairs Dept. Please respond to my previous e-mail asking for justification. If you cannot provide valid justification, we will cancel the line. Please advise. Thanks!



Bettina C. Dwor
Master Data Administrator
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Sent: Wednesday, June 26, 2013 2:05 PM
To: Bettina C Dwor
Subject: RE: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885

How many can you send without needing supporting documentation???

Cindy A. Willet
Sr. Buyer Generic & Branded Pharmaceuticals
Miami-Luken Inc.
265 S. Pioneer Blvd.
Springboro, OH 45066
Phone: 937-743-7775 x111
Fax: 888-884-4793
cwillet@miamiluken.com

From: Bettina C Dwor [<mailto:bettina.dwor@actavis.com>]
Sent: Wednesday, June 26, 2013 1:22 PM
To: cwillet
Cc: #Master Data Group; Vicky C Goldy; Maria Lesny; Bea Padilla; Judy L Callahan
Subject: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885

Hi Cindy, in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.

PO# 0446902 SD# 636885

00591082501 OXYCODONE/APAP 10/650MG TAB 100 – QTY 72

Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.

Any questions, let me know, please respond to Master.Data.group@watson.com.



Bettina C. Dwor
Master Data Administrator
Actavis
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Parsippany, NJ 07054
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6/26/13 SH080B
DIVISION 00ITEM SOLD REPORT
FROM 5/01/13 TO 0/00/00

PAGE 1

ITEM NO.	DESCRIPTION	CATEGORY	INVOICE NO.	INVOICE DATE	QTY	PRICE	NET	EXTENDED	TRANS
972422	EA 100 OXYCODONE APAP 10/650MG TAB OS	GEN							
CUSTOMER									
NO.	DESCRIPTION		NO.	DATE	QTY	PRICE		AMOUNT	CODE
9812	BATAVIA COMMUNITY PHCY		MLI 1641210	5/01/13	1	31.800		31.80	
4350	*ARENSBERG #2 W.CHURCH ST REM		MLI 1642230	5/06/13	3	31.800		95.40	
9925	SLONE'S DISCOUNT PHARMACY		MLI 1642511	5/07/13	2	31.800		63.60	
852600	LOOP PLAZA DISC PHARM RX		MLI 1642631	5/07/13	1	31.800		31.80	
9720	COMMUNITY PHARMACY		MLI 1643249	5/09/13	2	31.800		63.60	
9925	SLONE'S DISCOUNT PHARMACY		MLI 1643290	5/09/13	4	31.800		127.20	
36129	HIGHLAND SQUARE PHARMACY		MLI 1643682	5/10/13	2	31.800		63.60	
9779	MAPLE LEAF HILLTOP PHCY		MLI 1643694	5/10/13	1	31.800		31.80	
19785	TRUMBULL MAHONING MED GRP		MLI 1643697	5/10/13	2	31.800		63.60	
9954	MIDDLETOWN PHARMACY		MLI 1643974	5/13/13	1	31.800		31.80	
9958	MARWOOD LOW COST PHCY		MLI 1644051	5/13/13	4	31.800		127.20	
522288	*FAIRFIELD PHARMACY		REM 1644075	5/13/13	1	31.800		31.80	
9833	VALUE-MED, INC PNTSVL		MLI 1644351	5/14/13	5	31.800		159.00	
27200	HOMETOWN PHARMACY INEZ		/MLI 1644722	5/15/13	3	31.800		95.40	
9833	VALUE-MED, INC PNTSVL		MLI 1645058	5/16/13	3	31.800		95.40	
35430	MCMEANS #1 ASHLAND		MLI 1645089	5/16/13	5	31.800		159.00	
TEMPORARY SHORT									
852600	LOOP PLAZA DISC PHARM RX		MLI 1645111	5/16/13	2	31.800		63.60	
TEMPORARY SHORT									
9833	VALUE-MED, INC PNTSVL		MLI 1645766	5/20/13	6	31.800		190.80	
522288	*FAIRFIELD PHARMACY		REM 1646083	5/21/13	1	31.800		31.80	
852600	LOOP PLAZA DISC PHARM RX		MLI 1646202	5/21/13	2	31.800		63.60	
35430	MCMEANS #1 ASHLAND		MLI 1646475	5/22/13	5	31.800		159.00	
19785	TRUMBULL MAHONING MED GRP		MLI 1646888	5/23/13	2	31.800		63.60	
9833	VALUE-MED, INC PNTSVL		MLI 1646918	5/23/13	6	31.800		190.80	
38659	DELPHOS DISCOUNT DRUG		MLI 1647232	5/24/13	1	31.800		31.80	
23510	*GERMANTOWN PRESCRIP		REM 1647251	5/24/13	1	31.800		31.80	
20375	*EASTERDAY PHARMACY		REM 1647521	5/28/13	1	31.800		31.80	
TEMPORARY SHORT									
850650	DENNIS' PHARMACY @		MLI 1647638	5/28/13	3	31.800		95.40- CR MEMO	
9779	MAPLE LEAF HILLTOP PHCY		MLI 1647655	5/28/13	1	31.800		31.80	
9812	BATAVIA COMMUNITY PHCY		MLI 1648034	5/29/13	1	31.800		31.80	
9917	FAMILY DRUG WHEELWRIGHT		MLI 1648305	5/30/13	1	31.800		31.80	
35430	MCMEANS #1 ASHLAND		MLI 1648307	5/30/13	5	31.800		159.00	
TEMPORARY SHORT									
9954	MIDDLETOWN PHARMACY		MLI 1648379	5/30/13	2	31.800		63.60	
TEMPORARY SHORT									
696105	TUG VALLEY PHARMACY,LLC		MLI 1649020	6/03/13	4	31.800		127.20	
TEMPORARY SHORT									
35430	MCMEANS #1 ASHLAND		MLI 1649822	6/05/13	10	31.800		318.00	
TEMPORARY SHORT									
4350	*ARENSBERG #2 W.CHURCH ST REM		MLI 1649920	6/05/13	1	31.800		31.80	
TEMPORARY SHORT									
522288	*FAIRFIELD PHARMACY		REM 1650593	6/07/13	2	31.800		63.60	
TEMPORARY SHORT									
35445	MCMEANS #2 SOUTH POINT		MLI 1650669	6/07/13	3	31.800		95.40	
9779	MAPLE LEAF HILLTOP PHCY		MLI 1651011	6/10/13	1	31.800		31.80	
4350	*ARENSBERG #2 W.CHURCH ST REM		MLI 1651093	6/10/13	1	31.800		31.80	
36129	HIGHLAND SQUARE PHARMACY		MLI 1651455	6/11/13	1	31.800		31.80	

9925 SLONE'S DISCOUNT PHARMACY MLI 1651776 6/12/13 2 31.800 63.60
 35430 MCMEANS #1 ASHLAND MLI 1651841 6/12/13 12 31.800 381.60
 59884 WESTSIDE PHARMACY MLI 1652173 6/13/13 2 31.800 63.60
 852600 LOOP PLAZA DISC PHARM RX MLI 1652179 6/13/13 2 31.800 63.60
 696105 TUG VALLEY PHARMACY,LLC MLI 1652460 6/14/13 6 31.800 190.80
 522288 *FAIRFIELD PHARMACY REM 1652804 6/17/13 2 31.800 63.60
 35430 MCMEANS #1 ASHLAND MLI 1653496 6/19/13 5 31.800 159.00
 35445 MCMEANS #2 SOUTH POINT MLI 1653525 6/19/13 2 31.800 63.60
 696105 TUG VALLEY PHARMACY,LLC MLI 1653857 6/20/13 6 31.800 190.80
 6/26/13 SH080B ITEM SOLD REPORT PAGE 2
 DIVISION 00 FROM 5/01/13 TO 0/00/00

NO.	DESCRIPTION	CATEGORY	GEN				
972422	EA 100 OXYCODONE APAP 10/650MG TAB OS		GEN				
CUSTOMER	INVOICE	INVOICE	NET EXTENDED TRANS				
NO.	DESCRIPTION	NO.	DATE	QTY	PRICE	AMOUNT	CODE
716688	NORTHERN HILLS PHARMACY	MLI 1653910	6/20/13	5	31.800	159.00	
23510	*GERMANTOWN PRESCRIP	REM 1654221	6/21/13	4	31.800	127.20	
9954	MIDDLETOWN PHARMACY	MLI 1654284	6/21/13	4	31.800	127.20	
19785	TRUMBULL MAHONING MED GRP	MLI 1654292	6/21/13	3	31.800	95.40	
525188	YOST PHARMACY	MLI 1654594	6/24/13	1	31.800	31.80	
38659	DELPHOS DISCOUNT DRUG	MLI 1654638	6/24/13	2	31.800	63.60	
9958	MARWOOD LOW COST PHCY	MLI 1654954	6/25/13	3	31.800	95.40	
	ITEM SHIPPED	126 ***			4006.80	***	
	ITEMS OMITTED	32 ***			1017.60	***	

Produced as Natives

 Contract Entity Current

From: cwillet <cwillet@miamiluken.com>
Sent: Wednesday, June 26, 2013 11:21 AM
To: Bettina C Dwor
Subject: RE: Order(s) on Hold - MIAMI-LUKEN INC SD# 636885
Attachments: image003.gif; image004.gif; Oxycodone sales may-june '13.txt

Please find attached our sales for the month of May-present day June. We have 12 bottles in stock.

Let me know if you need anything further.

Cindy

Cindy A. Willet
Sr. Buyer Generic & Branded Pharmaceuticals
Miami-Luken Inc.
265 S. Pioneer Blvd.
Springboro, OH 45066
Phone: 937-743-7775 x111
Fax: 888-884-4793
cwillet@miamiluken.com

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To: cwillet
Cc: #Master Data Group; Vicky C Goldy; Maria Lesny; Bea Padilla; Judy L Callahan
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Hi Cindy, in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.

PO# 0446902 SD# 636885
00591082501 OXYCODONE/APAP 10/650MG TAB 100 – QTY 72

Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.

Any questions, let me know, please respond to Master.Data.group@watson.com.



Bettina C. Dwor
Master Data Administrator
Actavis
Morris Corporate Center III
400 Interpace Parkway, Bldg A
Parsippany, NJ 07054
P. 862.261.7071
F. 862.261.7808

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6/26/13 SH080B
DIVISION 00ITEM SOLD REPORT
FROM 5/01/13 TO 0/00/00

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CUSTOMER									
NO.	DESCRIPTION		NO.	DATE	QTY	PRICE		AMOUNT	CODE
9812	BATAVIA COMMUNITY PHCY		MLI 1641210	5/01/13	1	31.800		31.80	
4350	*ARENSBERG #2 W.CHURCH ST REM		MLI 1642230	5/06/13	3	31.800		95.40	
9925	SLONE'S DISCOUNT PHARMACY		MLI 1642511	5/07/13	2	31.800		63.60	
852600	LOOP PLAZA DISC PHARM RX		MLI 1642631	5/07/13	1	31.800		31.80	
9720	COMMUNITY PHARMACY		MLI 1643249	5/09/13	2	31.800		63.60	
9925	SLONE'S DISCOUNT PHARMACY		MLI 1643290	5/09/13	4	31.800		127.20	
36129	HIGHLAND SQUARE PHARMACY		MLI 1643682	5/10/13	2	31.800		63.60	
9779	MAPLE LEAF HILLTOP PHCY		MLI 1643694	5/10/13	1	31.800		31.80	
19785	TRUMBULL MAHONING MED GRP		MLI 1643697	5/10/13	2	31.800		63.60	
9954	MIDDLETOWN PHARMACY		MLI 1643974	5/13/13	1	31.800		31.80	
9958	MARWOOD LOW COST PHCY		MLI 1644051	5/13/13	4	31.800		127.20	
522288	*FAIRFIELD PHARMACY		REM 1644075	5/13/13	1	31.800		31.80	
9833	VALUE-MED, INC PNTSVL		MLI 1644351	5/14/13	5	31.800		159.00	
27200	HOMETOWN PHARMACY INEZ		/MLI 1644722	5/15/13	3	31.800		95.40	
9833	VALUE-MED, INC PNTSVL		MLI 1645058	5/16/13	3	31.800		95.40	
35430	MCMEANS #1 ASHLAND		MLI 1645089	5/16/13	5	31.800		159.00	
TEMPORARY SHORT									
852600	LOOP PLAZA DISC PHARM RX		MLI 1645111	5/16/13	2	31.800		63.60	
TEMPORARY SHORT									
9833	VALUE-MED, INC PNTSVL		MLI 1645766	5/20/13	6	31.800		190.80	
522288	*FAIRFIELD PHARMACY		REM 1646083	5/21/13	1	31.800		31.80	
852600	LOOP PLAZA DISC PHARM RX		MLI 1646202	5/21/13	2	31.800		63.60	
35430	MCMEANS #1 ASHLAND		MLI 1646475	5/22/13	5	31.800		159.00	
19785	TRUMBULL MAHONING MED GRP		MLI 1646888	5/23/13	2	31.800		63.60	
9833	VALUE-MED, INC PNTSVL		MLI 1646918	5/23/13	6	31.800		190.80	
38659	DELPHOS DISCOUNT DRUG		MLI 1647232	5/24/13	1	31.800		31.80	
23510	*GERMANTOWN PRESCRIP		REM 1647251	5/24/13	1	31.800		31.80	
20375	*EASTERDAY PHARMACY		REM 1647521	5/28/13	1	31.800		31.80	
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9812	BATAVIA COMMUNITY PHCY		MLI 1648034	5/29/13	1	31.800		31.80	
9917	FAMILY DRUG WHEELWRIGHT		MLI 1648305	5/30/13	1	31.800		31.80	
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 696105 TUG VALLEY PHARMACY,LLC MLI 1652460 6/14/13 6 31.800 190.80
 522288 *FAIRFIELD PHARMACY REM 1652804 6/17/13 2 31.800 63.60
 35430 MCMEANS #1 ASHLAND MLI 1653496 6/19/13 5 31.800 159.00
 35445 MCMEANS #2 SOUTH POINT MLI 1653525 6/19/13 2 31.800 63.60
 696105 TUG VALLEY PHARMACY,LLC MLI 1653857 6/20/13 6 31.800 190.80
 6/26/13 SH080B ITEM SOLD REPORT PAGE 2
 DIVISION 00 FROM 5/01/13 TO 0/00/00

ITEM	NO.	DESCRIPTION	CATEGORY	GEN			
972422	EA	100 OXYCODONE APAP 10/650MG TAB OS		GEN			
CUSTOMER		INVOICE	INVOICE	NET EXTENDED TRANS			
NO.	DESCRIPTION	NO.	DATE	QTY	PRICE	AMOUNT	CODE
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19785	TRUMBULL MAHONING MED GRP	MLI 1654292	6/21/13	3	31.800	95.40	
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	ITEM SHIPPED	126 ***			4006.80	***	
	ITEMS OMITTED	32 ***			1017.60	***	



**WATSON
Pharma, Inc.**

A Subsidiary of Watson Pharmaceuticals, Inc.
311 Bonnie Circle, P.O. Box 1900, Corona, CA 92878-1900
Tel: 800-272-5525 * Fax: 951-735-2871

Case: 1:17-md-02804-DAP Doc #: 2287-10 Filed: 08/13/19 16 of 16. PageID #: 360482

SOMS Investigation Form

Sales Order Date	Purchase Order #	Order #
06/26/2013	0446902	636885

Sold To #: 1201428

Name MIAMI-LUKEN INC
Street 265 PIONEER BLVD
City SPRINGBORO
State OH 45066

Ship To #: 1201428

Name MIAMI-LUKEN INC
Street 265 PIONEER BLVD
City SPRINGBORO
State OH 45066

Item #	Material #	Description	Order Qty	Sales Unit	Description	COT Avg./ord	COT Avg./mth	Cust Allow/ord	Cust Allow/mth	MTD Qty	Pending Qty	Release Qty	Reason Code
10	00591321472	FENTANYL PATCH 100MCG 5	24	5	EA	Suspect (Cus Av/mth)	138	32,551	63	91	72	0	24 12
30	00591321372	FENTANYL PATCH 75MCG 5	24	24	EA	Suspect (Cus Av/mth)	112	23,643	48	48	48	0	24 12
110	00591082501	OXYCODONE/APAP 10/650MG TAB 100	72	103	EA	Suspect (Cus Av/mth)	131	25,304	35	53	84	0	72

DEA Contacted / Date / Action

Signature

Customer Support Representative

Date

Manager Call Center Operations

Date

Location

☐

311 Bonnie Circle ,Corona, CA 92880
400 Interpace Parkway, Parsippany, NJ 07054

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